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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,561	12/08/2003	Sharad K. Govil	MTI 3.0-025 DIV DIV	4254

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EXAMINER	
WEBMAN, EDWARD J	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,561	GOVIL ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-111 and 113-119* is/are pending in the application.

4a) Of the above claim(s) *29-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28, 67-111, 113-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 67-76, 79-88, 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al (US 5,474,783).

Miranda et al teach a transdermal comprising a drug, an acrylate polymer and a polysiloxane (abstract). 2-96% polyacrylate and 98-4% polysiloxane is disclosed (column 4 lines 10-12). The acrylate polymer is composed of at least 50% alkyl acrylate monomer (column 9 lines 38-40). Butyl acryate is disclosed (column 9 line 44). The drug is 0.3-50% of the composition (column 8 line 67-column 9 line 2). Selegiline (al liquid) is disclosed (column 12 line 29). Propylene glycol and alcohols are disclosed as optional cosolvents (column 13 lines 43-54, Table II).

It would have been obvious to one of ordinary skill to make a composition comprising an acrylate to deliver selegiline to achieve the beneficial effect of

transdermal delivery in view of Miranda et al. As to the claimed hydrophobic acrylic polymer, Miranda et al teach at least 50% butyl acrylate as cited above, which renders the polymer hydrophilic.

Applicants argue no teaching to exclude solvents not driven off during drying. However, the process of making is not considered a patentable limitation during prosecution of composition claims before the USPTO. As to the solvents of claim 76, the above sited solvents will volatilize at a sufficiently high drying temperature.

Claims 67-70, 72, 73, 76, 79, 81, 82, 85-88, 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sablotsky (US 4,994,267).

Sablotsky teaches a transdermal comprising an acrylic polymer, a synthetic rubber, and a crosslinking agent (abstract). 5-95% acrylic polymer is specified (column 3 line 68-column 4 lines 1-2). At least 50% alkyl acrylate is specified (column 4 lines 20-21). Butyl acrylate is disclosed (column 4 lines 24-25). Polyisobutylene is disclosed as a rubber (column 5 lines 30-37). Nitroglycerin (a liquid) is specified as a drug (column 5 line 65). 0.1-50% drug is disclosed (column 6 lines 38-39). Optional cosolvents , including propylene glycol and alcohols, are disclosed (column 7 lines 58-65

It would have been obvious to one of ordinary skill to make a composition comprising an acrylate to deliver a drug to achieve the beneficial effect of transdermal delivery in view of Sablotsky. The statements as well as the response to applicants'

argument following the first 103 motivation to combine are incorporated herein as applied to Sablotsky.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8-10, 12-15, 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lhila et al (US 5,498,417).

Lhila et al teach a transdermal comprising a pressure-sensitive adhesive (abstract). Gelva 788 [disclosed in applicants' specification in example 15 and tables II and III] is specified (column 2 line 26). 25-90% polymer is disclosed (column 2 lines 28-30). 0.5%-15% each of triethanolamine and glycerol or polyalkylene glycol are disclosed (column 2 lines 39-52). Propylene glycol is specified (claim 1). 10-60% active is disclosed (column 2 lines 33-35).

Applicants argue that Lhila et al do not teach the claimed solvent properties, however, such properties must be possessed by the anticipatory composition because it is the same as that claimed.

Claims 1-9, 11-14, 16-28, 67-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter et al (US 5,462,746).

Wolter et al teach a transdermal comprising an adhesive, a drug or salt thereof, and, when the salt is present, an element containing basic groups (abstract). Deprenyl (selegeline) is disclosed (column 3 line 44). Ethyl acetate is specified (column 4 line 64). Glycerol, an optional solvent, is disclosed (column 2 line 55). DURO-TAK 2516 [disclosed in applicants' specification in Table III as an acrylate polymer comprising ethylhexyl acrylate and methyl acrylate, crosslinked with aluminum] is specified (column 5 line 9). Polydimethylaminoethyl methacrylate (Eudragit E) is disclosed (column 5 line 1-3). Ethanol is disclosed (column 5 lines 10-11).

It would have been obvious to one of ordinary skill to make a composition comprising deprenyl and an acrylate polymer to achieve the beneficial effect of transdermal delivery in view of Wolter et al. As to the claimed acrylate polymer, deprotonating agent, drug and solvent, it is argued that the composition is achieved when the drug and solvent of Wolter et al enter the matrix of DUROTAK 2516 and Eudragit E (see column 4 line 57-column 5 line 25). As to the claimed percent ranges of of acrylate polymer, non-aqueous solvent and drug, Wolter et al teach suitable amounts. Absent a showing of criticality, optimum suitable amounts may be obtained by routine experimentation.

Applicants argue that glycerol does not meet claim 67. However, it will volatilize at a sufficiently high drying temperature. Further, ethyl acetate and ethanol meet the claimed limitations as to volatility.

Claims 94-102, 104-111, 113 and118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 94 "a monomer" is vague; what kind?

In claims 98 and 118 "noniquous" in indefinite.

Claim 113 depends on a cancelled claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 17-21, 24-28, 67-111, 113 are rejected under 35 U.S.C. 102(e) as being anticipated by Mantelle et al (US 6,316,022).

Mantelle '022 teaches a transdermal comprising a liquid active and a polymer (abstract). Duro-Tak 87-2852 is disclosed (column 13 line 34), the same polymer as applicants teach (page 19 line 18). Selegiline is disclosed (column 3 line 6). Proranalol is specified (column 5 line 12). Propylene glycol is disclosed (column 5 line 67). Rubber and polysiloxanes are disclosed (column 8 lines 47, 61). 10-90% acrylate and 1-40% drug is specified (column 9 table 1). Ethanol and ethyl acetate are disclosed

(column 10 lines 60 and 62). 15% selegiline is specified (example 1). Urea is specified (column 6 line 5).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-75 and 101-102, 105-111 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 84, 86-94 of copending Application No. 08/883075 and 09/754909 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the '075 claims regarding the presence of additional unspecified essential ingredients and the patented claims and the '909 claims encompass the instant claims regarding the scope of the alkyl acrylates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor S. Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500